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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,953	05/10/2007	Guenter Bellmann	P04167	1499
23702 7590 04/14/2010 Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701				
EXAMINER CHOI, FRANK I				
ART UNIT 1616		PAPER NUMBER		
MAIL DATE 04/14/2010		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/583,953

**Applicant(s)**

BELLMANN ET AL.

**Examiner**

FRANK I. CHOI

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2009.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.  
4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1 and 3-11 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☒ Claim(s) 1 and 3-14 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Inventor's Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Newly amended claims 12-14 directed to methods of making and methods of supplementing the diet are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original claims were directed to products.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 12-14 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Objections***

Claims 10, 11 are objected to because of the following informalities: Claims should consist of single sentence ending in a single period mark. The subparagraph letters should not have period marks associated with the same. The examiner suggests single parenthesis after the letter or two parentheses surrounding the letter. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1, 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al. (US Pat. 6,579,544).

The claimed invention is directed to a product containing zeaxanthin, lutein, zinc, copper which is free of beta carotene.

Rosenberg et al. expressly discloses a dietary composition containing zeaxanthin, lutein, zinc, copper, vitamin C and vitamin E falling within the scope of the claimed invention:

# EXAMPLE

The following formulae represent specific embodiments of the invention. These embodiments can be prepared by blending together the stated dry raw materials in an agglomerator to result in a product having a uniform composition with the precise proportions of the components as indicated. More than one ingredient is oil-based, and such ingredients are preferably blended and distributed over the dry ingredients. If flax seed oil is to be added, said oil is mixed with the blended dry ingredients and oil-based ingredients, and the resulting mixture is a product having a uniform composition. The agglomerated material is then preferably placed in capsules according to methods well known in the art, such as is summarized in Remington's Pharmaceutical Sciences, in quantities of one ration per capsule. As a frame of reference, Formulation II, as set out below, is intended to be encapsulated in 7 "00" capsules, each containing about 1.0 to 1.3 g/ml. Other formulations can be encapsulated in any suitable number and size of capsules, in accordance with the knowledge of one of ordinary skill in the relevant art of capsule sizing and quantifying. Size "00" capsules have a capsule volume of about 0.95 ml. Other capsule sizes could be selected according to principles well known in the pharmaceutical arts. In the preferred embodiment, the composition comprises the following ingredients stated in amounts by weight or international units (IU):

Ingredients	Formulation Number							
	I	II	III	IV	V	VI	VII	VIII
Vitamin A (IU)	2000	10,000		8000		5000		
Vitamin D (IU)	125	400		500		600		
Vitamin E (IU)	250	400	600	300	550	700	400	500
Vitamin K (µg)	300	80		20		50		
Vitamin C (mg)	500	1500	2000	1000	1500	750	1200	600
Thiamine (mg)	50	10			5	1		
Riboflavin (mg)	50	10			5	1		
Niacin (mg)	50	40			10	20		
Pyridoxine (mg)	1	20			40	30		
Folate (µg)	100	600			900	200		

Art Unit: 1616

-continued

Ingredients	Formulation Number							
	I	II	III	IV	V	VI	VII	VIII
Vitamin B-12 (µg)	5	25			50	30		
Biotin (µg)	100	400			800	500		
Pantothenic Acid (mg)	100	20			5	30		
Ca (mg)	1500	1000	800	500	1200	1000	1300	800
Mg (mg)	100	400		500		800		
Cr (µg)	300	150				10		200
Cu (mg)	1	3				5		1
I (µg)	10	150				300		50
Fe (mg)	2	5				10		5
Mn (mg)	50	10				1		30
Mo (µg)	200	75				10		100
Se (µg)	20	200				500		100
Zn (mg)	5	20				100		50
B (mg)	2	1				5		0.5
V (µg)	20	10				1		50
α-Carotene (µg)	400	196		20				200
β-Carotene (mg)	1	6		8			10	
Cryptoxanthin (mg)	100	49	20		90			
Lutein (mg)	5	10		20	10	15		25
Lycopene (mg)	1	2		10	5			
Zeaxanthin (µg)	800	539		200				600
Citrus Bioflavonoids (mg)	150	50					10	100
Grape Seed Extract (mg)	5	25					100	50
Quercetin (mg)	100	25					100	50
Rutin (mg)	5	25					100	75
Soybean Isoflavones (mg)	100	62					250	10
Flax Seed Oil (mg)	1000	500				100		2000
Glucoamine (mg)	500	750				1000		200
Chondroitin (mg)	1000	600				150		1200
α-Lipoic Acid (mg)	25	50			100		5	
Coenzyme Q10 (mg)	25	10					5	50

Further, it is disclosed that various compounds can be added that are useful in the manufacture of nutritional supplements, including lactose, dyes, etc. and that tablets can be prepared (Column 25). The effective amounts of carotenoid, such as Beta-carotene, lutein and

zeaxanthin, Vitamin E, vitamin C, zinc and copper are disclosed (Column 3, Column 5, lines 47-68, Column 6, lines 1-25).

Rosenberg et al. discloses nutritional supplements containing zeaxanthin, lutein, zinc, copper, vitamin C and vitamin E. The difference between Rosenberg et al. and the claimed invention is that Rosenberg et al. does not expressly disclose adding a coating substance, the specific amounts or the exclusion of beta-carotene. However, the prior art amply suggests the same as Rosenberg et al. discloses that dyes can be added, that the composition is suitable for nutritional supplementation, effective amounts and lists beta-carotene as an alternative carotene. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to add a dye to distinguish the product visually, would have been motivated to use various amounts of the claimed active agents in order to meet the varying needs of the person or persons taking the nutritional supplement and would have expected that the supplement would not require the use of beta-carotene as it is disclosed in the alternative.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant argues that the prior art does not disclose the combination of lutein, zeaxanthin, copper and zinc which is free of beta-carotene or the daily dosage amounts. However, as indicated above, Rosenberg et al. does disclose the combination of lutein, zeaxanthin, copper and zinc which does not require the addition of beta-carotene. Further, as indicated above, Rosenberg et al. discloses effective amounts of the same. The Applicant has not provided evidence of the criticality of the claimed ranges. As such, it is well within the skill of

one ordinary skill in the art to arrive at various amounts, including those claimed, depending on the nutritional needs of the person.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. The Examiner maintains a flexible schedule, however, the Examiner may generally be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
April 14, 2010

/Johann R. Richter/



Application/Control Number: 10/583,953

Page 8

Art Unit: 1616

Supervisory Patent Examiner, Art Unit 1616